

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional) 8627/1318 (PA-5360-RFB)		
<p>I hereby certify that this correspondence is being electronically deposited pursuant to 37 CFR 1.8(a) with the United States Patent and Trademark Office through the Electronic Filing System, on the below date:</p> <p>On: <u>November 4, 2009</u></p> <p>Signature: <u>/Janet A. Pioli/</u></p> <p>Typed or printed name: <u>Janet A. Pioli</u></p>		Application Number	Filed	
		10/719,415	November 21, 2003	
		For: <u>Stent tissue graft prosthesis</u>		
		First Named Inventor <u>Dusan Pavcnik</u>		
		Art Unit	Conf. No.	Examiner
		3738	3409	Christopher D. Prone
<p>Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.</p> <p>This request is being filed with a Notice of Appeal.</p> <p>The review is requested for the reason(s) stated on the attached sheet(s). Note: No more than five(5) pages may be provided.</p> <p>I am the:</p> <p><input type="checkbox"/> Applicant/Inventor. <u>/Janet A. Pioli/</u> Signature</p> <p><input type="checkbox"/> Assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)</p> <p><input checked="" type="checkbox"/> Attorney or agent of record. Registration No. <u>35,323</u></p> <p><input type="checkbox"/> Attorney or agent acting under 37 CFR 1.34. Registration No. if acting under 37 CFR 1.34. _____</p> <p><u>Janet A. Pioli</u> Typed or Printed Name</p> <p><u>312-321-4725</u> Telephone number</p> <p>Note: Signatures of all inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below.*</p> <p><input checked="" type="checkbox"/> *Total of <u>one</u> forms are submitted.</p>				
		<p><u>November 4, 2009</u> Date</p>		

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Date: November 4, 2009 Name: Janet A. Pioli, Reg. No. 35,323 Signature: /Janet A. Pioli/

Attorney Docket No. 8627/1318

Client Ref. No. PA-5360-RFB

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Dusan Pavchnick)
Serial No. 10/719,415)
Filing Date: November 21, 2003) Examiner: Christopher D. Prone
For: Stent Tissue Graft Prosthesis) Group Art Unit No.: 3738
Confirmation No.: 3409

PRE-APPEAL BRIEF REQUEST FOR REVIEW

Mail Stop AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Applicants request review of the file of the above-identified application, for the reasons stated in the attached sheets. No amendments to the claims are filed with this request. Applicants also file a Notice of Appeal along with this request. No more than five (5) pages are provided.

I. Background

A. The Rejections

Claims 1, 4-12, 14, 16-18 and 20-22 are pending in the application. Claims 1, 20, 21 and 22 are independent. In the Final Office Action dated July 10, 2009, ("Office Action"), the Examiner rejected claims 1, 4-11, 14, 17-18 and 20-22 as unpatentable over U.S. Patent No. 5,865,723 ("Love") in view of U.S. Patents No. 5,891,193 ("Robinson et al.") and 5,628,788 ("Pinchuk"). The Examiner rejected claims 4-5 and 7-8 as unpatentable over Love in view of Robinson et al. and Pinchuk, and further in view of U.S. Patent No. 6,358,284 (Fearnot et al.). The Examiner also rejected claims 1, 12 and 16 as unpatentable over Pinchuk in view of Fearnot et al. and further in view of Love.

B. The Claims

Claims 1, and 20-22 are independent. In their current state, independent claims 1, 20, 21, 22 all require at least:

1. a first (inner) stent (claims 1, 20-22);
2. a tissue graft (claims 1 and 21), or a multi-layer tissue graft (claims 20 and 22) disposed on the first stent, but not secured to the first stent,
3. the tissue graft having properties of eversion if not supported (claims 1, 20-22);
4. a tubular member, or a second (outer) stent disposed over the tissue graft and around the first stent (claims 1, 20-22);
5. retaining the tissue graft on the first stent solely by compressive forces (claims 1, 20-22);
6. the compressive forces are provided at least by an outward expansion of the first stent (claims 1, 20-22);
7. distal and proximal tubular member (second stent) ends that are substantially coincident with the respective distal and proximal first stent ends (claims 1, 20-22);
8. distal and proximal first stent ends at least coincident with the distal and proximal ends of the tissue (claims 1 and 20) or they extend beyond the ends of the tissue (claims 21 and 22); and
9. that during and after implantation the most distal tissue graft end and the most proximal graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first stent (claims 1, 20-22).

To make a *prima facie* case of obviousness, the Examiner must show that the references, either alone or in combination, disclose or suggest every single one of these elements. The Examiner has not met his burden. As demonstrated here, none of the cited references, either alone or in any conceivable combination disclose **all** of these claims elements.

During the interview of March 30, 2009, Applicants' representatives emphasized that none of the cited references, alone or in combination teach 1) a *tissue graft* or a multi-layer *tissue graft* that has the *property of eversion* upon placement in a blood vessel if not supported, and 2) a tubular member, which is disposed over the tissue graft and around the first stent and *that retains the tissue graft disposed on the first stent solely by compressive forces* without any other attachment mechanism. The Examiner suggested that Applicants further amend the independent claims to clarify that *the compressive forces are provided at least by an outward expansion of the first stent*. The Examiner agreed to enter the proposed claim amendments and indicated that such claim

amendments would likely distinguish Applicants' invention from the cited references. Notwithstanding, the Examiner issued a final rejection of the claims in the Office Action dated July 10, 2009.

For purposes of the present brief, in the interest of space, Applicants do not specifically address the additional features recited in dependent claims 4-12, 14, 16, or 18. Applicants reserve the right to argue on Appeal that devices with the features recited in these claims are also nonobvious over the cited art.

II. The Rejection of the Claims Is Improper

A. Claims 1, and 20-22 are not Obvious Over Love in View of Either or Both Robinson and Pinchuk

The Examiner rejects claims independent claims 1, and 20-22 as obvious over Love in view of Robinson and Pinchuk. The Examiner has failed to show a *prima facie* case of obviousness. MPEP 2142 requires that "[t]o establish a *prima facie* case of obviousness . . . the prior art reference[s] . . . must teach or suggest **all** the claim limitations. *In re Vaeck*, 947 F.2d 488, 20 USPQ 2d 1428 (Fed. Cir. 1991). Contrary to the Examiner's assertion, the combination of these references does not teach or suggest all of the claim limitations.

First, the Examiner acknowledges that the primary reference, Love, **does not** disclose all of the features of the claims. Specifically, the Examiner admits that Love does not disclose (1) the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft or (2) that the inner stent expands to provide the compressive force." (7/10/09 Office Action, p. 3). The Examiner previously pointed out that Love lacks a third element: "Love does not disclose that the distal and proximal most portions of the first stent are at least coincident with or extend beyond the distal and proximal most ends of the graft or that the implant is held together . . . solely by compressive forces." (12/22/08 Final Office Action, p. 2). Hence, Love is lacking at least three elements of the claims.

In addition, as set forth above, during the interview, the Examiner suggested adding that the compressive forces are provided at least by an outward expansion of an inner stent to distinguish over the cited references. In the present rejection, the Examiner relies on Robinson to provide the first missing element and Pinchuk to provide the second. (7/10/09 Final Rejection, p. 3.) However, the Examiner cites nothing that discloses the claim element that the compressive forces are provided at least by an outward expansion of an inner stent. Love discloses at column 8, lines 17-30 that the outer helix may be expanded and placed over a mandrel having the first inner helix and

the graft material, and then allowing the outer helix to contract onto graft. This is contrary to Applicants' claim, which recites that the compressive forces are provided at least by and outward expansion of the inner stent.

Neither Pinchuk nor Robinson, alone or in combination, cure the deficiencies of Love. Specifically, with regard to Pinchuk, the Examiner is not only wrong about what Pinchuk purportedly teaches, but the Examiner has clearly admitted in the present Final Rejection as well as the previous rejection that "Pinchuk does not disclose" that the elements of the prosthesis "are held together **solely** by compressive forces." (Final Rejection, p. 4; 12/22/08 Office Action, p. 4) (Emphasis added). Moreover, Pinchuk does not disclose or teach that the compressive forces are provided at least by an outward expansion of the first stent. Finally, Pinchuk teaches that the stent is affixed to the tubular material (graft) by adhesive. Hence, Pinchuk **teaches away** from a prosthesis where the graft is retained on the stent **solely** by compressive forces.

Robinson also does not teach these missing claim elements and further does not make up for the deficiencies of Love and Pinchuk. Robinson does not teach does not teach an inner stent and an outer tubular member (outer stent) with a tissue graft disposed therebetween. Robinson does not teach retaining a graft on the inner stent solely by compressive forces or that the compressive force is provided at least by an outward expansion of an inner stent. At column 6, lines 55-67, Robinson states that the anchor is sutured to the graft. At column 7 lines 38-column 8, lines 1-5, Robinson discloses only that a margin of the graft may captured between two anchor segments, with one of the anchor segments running through a hole in the graft. Nothing in Robinson states that the margin is retained on the graft solely by compressive forces or that the compressive force is provided at least by an outward expansion of an inner stent.

Moreover, none of the references teach or suggest a tissue graft tissue graft having properties of eversion if not supported or that that during and after implantation the most distal tissue graft end and the most proximal graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first stent. Finally, none of the references teach or suggest that the distal and proximal tubular member (second stent) ends are substantially coincident with the respective distal and proximal first stent ends claims **and** that the distal and proximal first stent ends are at least coincident with the distal and proximal ends of the tissue (claims 1 and 20) or that they extend beyond the ends of the tissue (claims 21 and 22).

The Examiner has not made a *prima facie* showing of obviousness as the combination of references relied on lack multiple claim elements.

B. Claims 1, 12, and 16 are not Obvious Over Pinchuk in View of Fearnot and Further in View of Love

The Examiner rejects claims 1, 12, and 16 as obvious over Pinchuk in view of Fearnot and Love. Again, due to the page limitation, Applicants discuss only independent claim 1. As set forth above, the Examiner admits that Pinchuk does not disclose that a tissue graft retained on the first stent solely by compressive forces. Pinchuk also does not disclose that those forces are provided at least by an outward expansion of an inner stent. Fearnot does not disclose either of these elements. The Examiner admits that Love does not disclose that those forces are provided at least by an outward expansion of an inner stent, and indeed, encouraged Applicants to so amend their claims. As set forth above, neither Love nor Pinchuk a tissue graft tissue graft having properties of eversion if not supported or that that during and after implantation the most distal tissue graft end and the most proximal graft end remain substantially in the pre-implantation configuration such that the tissue graft does not evert or fold into the passage of the first stent. Fearnot only discloses a multi-layer graft and no other elements of claim 1.

III. Conclusion

For at least these reasons, Applicants request review of the final rejection in the current application, withdrawal of all of the rejections against the pending claims, and a re-opening of prosecution. Applicants believe that the present claims are patentable and that the application is in a condition for allowance. Accordingly, Applicants respectfully request that the Examiner grant allowance of the application. The Examiner is invited to contact the undersigned attorney for the Applicants via telephone if such communication would expedite this application.

Respectfully submitted,

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